IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES ex rel. LAURIE SIMPSON, *Plaintiff,*	:	Honorable Jose L. Linares United States District Court Judge
v.	:	Civ. No. 05-3895
BAYER CORPORATION; BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER HEALTHCARE LLC; and BAYER AG, *Defendants.*	:	

THE UNITED STATES' STATEMENT OF INTEREST
AS TO DEFENDANTS' MOTION TO DISMISS

The United States, the real party in interest in this action, respectfully submits this Statement of Interest pursuant to 28 U.S.C. § 517 to respond to certain arguments made by the defendant Bayer Corporation, Bayer HealthCare Pharmaceuticals, Inc., and Bayer HealthCare LLC (collectively, "Bayer") in its Motion to Dismiss. The United States remains a real party in interest in this matter, even though it has not intervened in the action. *United States ex rel. Karvalas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004). The False Claims Act (FCA), 31 U.S.C. § 3729 et seq., is the United States' primary tool used to redress fraud on the government. The United States has a keen interest in the development of the law in this area and in the correct application of the law in this, and similar, cases.

The United States takes no position on Bayer's arguments concerning the Court's subject matter jurisdiction, Simpson's state and local claims, the statutes of limitation, or Simpson's employment related claims. Rather, should the Court reach beyond these arguments, the United

States submits this Statement of Interest for the purpose of clarifying its position with respect to three issues: 1) the circumstances under which the marketing of prescription drugs or violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, may give rise to an actionable claim under the False Claims Act ("FCA"), 31 U.S.C. § 3729; 2) reimbursement under a Diagnosis Related Group (DRG) does not preclude liability under the FCA; and 3) the proper standard for assessing the sufficiency of Simpson's misbranding and AKS claims under Fed. R. Civ. P. 9(b).

I. Promotion of Prescription Drugs For Non-Covered Uses or Violations of the AKS May Give Rise to Actionable Claims Under the FCA.

Relator Simpson alleges that Bayer illegally promoted Trasylol for unapproved or off-label uses without updating the label. *See* Relator's Opposition to Defendant's Motion to Dismiss (Rel. Opp.) at 2-3. Bayer contends that Simpson's allegations fail because Simpson "cannot allege that this supposed misbranding would have led to a healthcare provider's false certification for compliance with a 'condition of payment.'" Def. Mem. at 23. Bayer further argues that "no provision of law requires the government to withhold payment of claims for FDA-approved drugs purportedly misbranded or marketed off-label, or refuse payment as a direct purchaser." *Id.*

As Bayer observes, not every violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. § 301 *et seq.*, or FDA regulations is a *per se* violation of the FCA because not every such violation has a nexus to payment. Contrary to Bayer's argument, however, a manufacturer's off-label promotion of prescription drugs can give rise to an actionable claim under the FCA because a manufacturer's conduct can knowingly cause the submission of prescription drug claims that are "false" under the FCA. The FCA imposes liability on any manufacturer that knowingly causes the submission of a false or fraudulent claim to federal

health care programs. 31 U.S.C. § 3729(a). A claim can be false or fraudulent under the FCA for any number of reasons. One way a claim can be "false" is if it is not "covered" or "reimbursable" under a federal health care program.[1]

Under the FCA, a claim is "false" if, among other things, it seeks payment for treatment that is not statutorily eligible for reimbursement. Generally, Medicare covers only reasonable and necessary medical items and services. *See* 42 U.S.C. § 1395y(a)(1)(A). Indeed, the Medicare statute contains an express condition that "no payment may be made" for items or services which "are not reasonable and necessary for the diagnosis and treatment of illness or injury." *Id.*; 42 C.F.R. § 411.15(k)(1); *see also Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (recognizing that this provision "precludes reimbursement for any items or services . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury"). Medicare's guidance regarding coverage of an off-label use of a drug under the Part B benefit similarly ties coverage to medical necessity. That guidance provides that coverage is only appropriate where the off-label use is "medically accepted," taking into account certain drug compendia (e.g., Drugdex, American Hospital Formulary Service, and U.S. Pharmacopeia-Drug Information), authoritative medical literature, and/or accepted standards of medical practice. See Medicare Benefit Policy Manual, Ch. 15, § 50.4.2. Medicaid similarly ties coverage to whether an off-label use is medically accepted based on supportive citations in certain drug compendia. 42 U.S.C. § 1396r-8(k)(6).[2]

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[1] Contrary to Bayer's suggestion, it is not necessary to show that the "alleged regulatory violations would have resulted in the withdrawal of regulatory approval for Trasylol." Def. Mem. at 23. Rather, the relator need only show that Bayer knowingly caused the submission of false, *i.e.*, non-reimbursable prescription claims for Trasylol.

[2] Mere listing in a compendium may not be sufficient, by itself, to render an off-label use "medically accepted." *See, e.g.*, Medicaid State Rebate Release #141 (May 4, 2006) (clarifying that that the Medicaid Drug Rebate Statute requires coverage of off-label uses of FDA-approved drugs for indications that are "supported (as opposed to listed) in" the statutory compendia). For example, citations regarding a particular off-label use included in a compendium may be negative. It would be anomalous to then view such a use as "medically accepted," i.e., "supported" by a citation in the compendia.

Courts have held that when a healthcare provider prescribes a drug for a use that is not covered by federal programs such as Medicare or Medicaid, the provider's claim for reimbursement of that prescription is "false" under the FCA. *See United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 51-53 (D. Mass. 2001) ("*Parke-Davis I*") ("The alleged FCA violation arises - not from unlawful off-label marketing activity itself - but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct."); *United States ex rel. Strom v. Scios*, 676 F. Supp. 2d 884, 891(N.D. Cal. 2009) ("Because the [Medicare] statute permits reimbursement only for 'reasonable and necessary' treatments, [an off-label prescription] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement. This satisfies the FCA's requirement of a 'false' statement."); *see also Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) (finding that submission of claims for services not covered by Medicare violated the FCA). Thus, Bayer is incorrect when it asserts that an express "false certification" must be alleged, *see* Def. Mem. at 26, because whether the provider "certified" on the claim for payment that the prescribed usage was "on-label" or otherwise reimbursable is irrelevant. Rather, the core question for "falsity" under the FCA is whether the government received a claim for payment from a healthcare provider for an item or service that was not legally reimbursable.

Bayer similarly suggests without any supporting authority that, despite the statute's express prohibition on payment for items that are not reasonable and necessary, the government may not withhold payment "so long as the patient and the provider reasonably understood the use to be 'reasonable and necessary.'" Def. Mem. at 25. As explained above, coverage is not determined simply by a physician's determination that a service or item was medically reasonable and necessary; rather, the determination of what is reasonable and necessary for purposes of Medicare coverage is committed to the discretion of the Secretary of the Department

of Health and Human Services. Numerous courts have recognized that, even when a physician believes a procedure is medically reasonable and necessary, that alone is not sufficient to require Medicare to pay for the procedure. *See, e.g.*, *Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989) ("[T]he Medicare statute does not require coverage for all medically necessary procedures . . . ."); *Svidler v. Dept. of Health and Human Servs.*, No. C 03-3593 MJJ, 2004 WL 2005781, at *5 (N.D. Cal. Sept. 8, 2004) ("Plaintiff then argues that because she is allowed to prescribe off label uses, Medicare must pay for off label uses. This leap of logic is unwarranted."); *see also Int'l Rehab. Scis., Inc. v. Sebelius*, 688 F.3d 994, 1002-03 (9th Cir. 2012) (affirming denial of Medicare coverage for failure to demonstrate the device was "safe and effective," despite FDA clearance and the assignment of a billing code and fee schedule); *Almy v. Sebelius*, 679 F.3d 297, 301, 306, 307 n.3 (4th Cir. 2012) (same); *United States ex rel. Dickson v. Bristol Myers Squibb Co.*, 289 F.R.D. 271, 274 (S.D. Ill. 2013) ("[T]he fact a drug is FDA-approved, does not mean it is 'reasonable and necessary' in every instance it is prescribed."); *Strom*, 676 F. Supp. 2d, at 891-92. When the Secretary has made the determination that a service is not reasonable and necessary, claims demanding payment for such services are not eligible for payment and are thus false under the FCA .

Simpson further alleges that Bayer resorted to various kickback schemes to influence physicians to prescribe the use of Trasylol as well as the drug Avelox. *See* Relator's Seventh Amended Complaint at 45-52, 60-68. Assuming, *arguendo*, Simpson can establish an underlying violation of the AKS, all claims tainted by those kickbacks are false as a matter of law because they violate a fundamental condition of payment. *See Wilkins*, 659 F.3d at 313 ("We disagree with the District Court to the extent that it held that compliance with the AKS was not a condition for payment under the federal health insurance program."). Moreover, the presence of a "false certification" is not necessary to render a claim tainted by kickbacks false.

What makes a claim "false" is its ineligibility for payment, triggered by the defendant's violation of a condition of payment. *See United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377 (1st Cir. 2011).

Bayer further argues that Simpson has not pled causation as to her kickback and misbranding claims. *See* Def. Mem. at 31-38. Defendants misconstrue the applicable causation standard in FCA cases. Under general tort law principles, causation is satisfied if the defendants' conduct was a substantial factor in producing the false claims and it was foreseeable that false claims would result. *See, e.g.*, *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004) (knowingly assisting in causing the government to pay claims grounded in fraud actionable under FCA); *United States ex rel. Franklin v. Parke-Davis*, No. Civ. A. 96-11651 PBS, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003) (foreseeable that non-fraudulent off-label promotion of pharmaceutical product would result in false Medicaid claims). *See also Allison Engine Co. v United States ex rel. Sanders*, 553 U.S. 662 (2008) (noting that a defendant is responsible for the "natural, ordinary, and reasonable consequences of his conduct"). Nor is there a requirement that the relator identify a specific statement that induced a specific claim. Like any other element of a case, causation can be established by circumstantial evidence sufficient to allow a reasonable jury to conclude that it is more likely than not that a causal connection existed. A defendant could reasonably foresee that employing an army of sales representatives to promote a drug for a particular indication and concealing known safety risks associated with that indication could cause providers to use the drug for that indication. Likewise, a jury could infer that the defendant's promotion and concealment were substantial factors in the physician's decision to use the device and ultimately submit claims for reimbursement. *See In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 39 (1st Cir. 2013) ("Pfizer has always known that, because of the structure of the American health care

system, physicians would not be the ones paying for the drugs they prescribed. Pfizer's fraudulent marketing plan, meant to increase its revenues and profits, only became successful once Pfizer received payments for the additional Neurontin prescriptions it induced. Those payments came from Kaiser and other [third-party payors].").

The United States takes no position as to whether Simpson has properly alleged a violation of the AKS, but to the extent she has, then dismissal at this stage would be inappropriate.

II. Reimbursement Under a Diagnosis Related Group (DRG) Does Not Necessarily Preclude Claims Under the FCA.

Bayer argues in its motion that any misrepresentations it may have made cannot, as a matter of law, be material to government payment for Trasylol because government programs reimburse providers for that drug as part of a Diagnosis Related Group (DRG), rather than reimbursing for it individually. *See* Def. Mem. at 26-27. In other words, even if a drug is dangerous and defective, Bayer contends that no false claims could ever result from its misrepresentations relating to that drug unless the drug is separately reimbursed. Bayer's argument is incorrect. In essence, Bayer contends that if CMS reimburses for a drug as part of a bundled payment, no false claims could ever result from the use of such drug, regardless of whether the drug was unapproved, defective, or dangerous. The mechanics of reimbursement cannot and should not be used to insulate a defendant from liability. *See United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) ("If a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork."); *Hutcheson,* 647 F.3d at 394-95 ("Blackstone's argument that Medicare would excuse these violations because of a bureaucratic [payment] mechanism. . .impermissibly cabins what the government may consider material."). Even when

reimbursement for a product is incorporated within the overall reimbursement for a procedure, the Secretary retains broad discretion to assess its reasonableness and necessity. Thus, the concealment of safety information that would have been material to the decision of federal healthcare programs to reimburse for procedures using the drug could be part of a set of facts stating a claim for violation of the FCA.

III. Relators Can Satisfy Their Pleading Requirements by Alleging a Fraudulent Scheme with Particularity.

Defendants argue that relator's complaint fails to allege fraud with sufficient particularity in that relator has not identified any specific false claims resulting from defendants' alleged conduct. Def. Mem. at 23. However, the allegation of a specific false claim is not an absolute prerequisite to pleading a viable FCA claim. Whether specific claims must be identified for a complaint to satisfy Rule 9(b)'s particularity requirement will depend on the circumstances of each case. *See United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009) ("That fraudulent bills were presented to the Government is the logical conclusion of the particular allegations in [relator's] complaint even though it does not include exact billing numbers or amounts."); *United States ex rel. Lusby v. Rolls Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) ("We don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit."); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007). When a complaint sets forth with particularity allegations of a fraudulent scheme or course of conduct allowing a plausible inference that false claims were presented to the federal government, it is not also necessary to identify specific claims because doing so adds little to the sufficiency of the complaint as a whole. *See United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 2006 WL 2642518, at *7 (W.D. Pa. 2006) ("[T]he falsity of the instant claims does not turn on anything unique to any individual claim or that would be

revealed from an examination of any claim, but rather the claims 'are false because of the improper financial arrangements between [defendant] and the physicians.'").

This is all the more appropriate in the context of an FCA action based on an underlying violation of the AKS. As noted above, in this type of case, claims are not rendered false because of anything particular to any individual claim. Rather, they are false because they are the result of a kickback. Thus, nothing is gained by requiring the relator to identify specific claims individually. *See, e.g.*, *Singh*, 2006 WL 2642518 at *7 ("The addition of specific identifying information of each claim adds little to complete the description of the scheme since the fraudulent conduct at issue does not rely on any specific claim."). Similarly, in an off-label case, where the alleged false claims were submitted not by the defendant, but instead by a third party, a relator "need not allege the details of particular claims, so long as 'the complaint as a whole is sufficiently particular to pass muster under the FCA.'" *See Rost*, 507 F.3d at 732 (*quoting Karvalas*, 360 F.3d at 225).[3]

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[3] If the Court does dismiss the case based on Rule 9(b), however, the dismissal should be without prejudice to the United States, as the United States has no role in preparing a relator's complaint and should not be barred from pursuing claims in the future because a relator's complaint failed to pass muster under Rule 9(b). *See United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 456 (5th Cir. 2005) ("[D]ismissal with prejudice as to the United States was unwarranted where, as here, the relator's claims were dismissed on a Rule 12(b)(6) motion based on a lack of specificity in the complaint as required by Rule 9(b).").

Dated: June 18, 2013

Respectfully submitted,

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